DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 29, 2015

Summit MedVentures
% Mr. Kenneth C. Maxwell II
Empirical Testing Corp.
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K150188
Trade/Device Name: SMV Scientific 4.5 mm Bone Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: April 3, 2015
Received: April 6, 2015

Dear Mr. Maxwell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K150188

Device Name
SMV Scientific 4.5mm Bone Screws

Indications for Use *(Describe)*

The SMV Scientific 4.5mm Bone Screws are intended to treat fractures of various bones including the clavicle, scapula, pelvis, long bones (humerus, ulna, radius, femur, tibia, and fibula), and small bones (metacarpals, metatarsals, and phalanges).

Type of Use (Select one or both, as applicable)
☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(K) SUMMARY

Submitter's Name	SMV Scientific
Submitter's Address	111 Sandra Muraida Way Unit 18A Austin, TX 78703
Submitter Contact Person	Nephi Zufelt Chief Technology Officer 512-750-8622
Empirical Consulting Contact Person	Kenneth C. Maxwell II Empirical Testing Corp. 719.291.6874
Date Summary was Prepared	16 April 2015
Trade or Proprietary Name	SMV Scientific 4.5mm Bone Screw
Common or Usual Name	Screw, Fixation, Bone
Classification	Class II per 21 CFR §888.3040 Device Classification
Product Code	HWC
Classification Panel	Division of Orthopedic Devices

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The SMV Scientific 4.5mm Solid Bone Screws consist of cortical screws in a variety of lengths to accommodate different anatomic sizes of patients. The screws are provided non-sterile and are self-tapping. Screws are manufactured from stainless steel.

INDICATIONS FOR USE

The SMV Scientific 4.5mm Bone Screws are intended to treat fractures of various bones including the clavicle, scapula, pelvis, long bones (humerus, ulna, radius, femur, tibia, and fibula), and small bones (metacarpals, metatarsals, and phalanges).The indications for use for the 4.5mm Bone Screw is similar to that of the predicate devices.

TECHNOLOGICAL CHARACTERISTICS

The SMV Scientific 4.5mm Bone Screw is made from stainless steel that conforms to ASTM F138. The subject and predicate device have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically the following characteristics are identical between the subject and predicates:

- Indications for Use
- Materials
- Principles of Operation

Table 5-1 Predicate Device

510k Number	Trade or Proprietary or Model Name	Manufacturer	Type
K092889	Osteo-Plate and Screw Fixation	Syntec	Primary

PERFORMANCE DATA

The SMV Scientific 4.5mm Bone Screw has been tested in the following test modes:

- Static Torsion per ASTM F543
- Driving Torque per ASTM F543
- Pullout Testing per ASTM F543
- Removal Torque per ASTM F543

The results of this non-clinical testing show that the strength of the SMV Scientific 4.5mm Bone Screw is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the SMV Scientific 4.5mm Bone Screw is substantially equivalent to the predicate device.